EXHIBIT 38

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	)	
This document relates to:	)	MDL No. 2804
The County of Cuyahoga v. Purdue Pharma L.P., et al., Case No. 17-OP-45004 (N.D. Ohio)	)	Case No. 17-md-2804
The County of Summit, Ohio, et al. v. Purdue Pharma L.P. et al., Case No. 18-OP-45090 (N.D. Ohio)	)	Hon. Dan Aaron Polster

REPORT OF KARL C. COLDER

I. INTRODUCTION AND SUMMARY OF OPINIONS

A. Qualifications

1. Overview

In my 32 years with DEA, I gained extensive investigative and leadership experience while rising steadily through the ranks to become Special Agent in Charge of the Washington Field Division. After receiving a B.A. in Political Science and Social Relations/Criminal Justice from Cheyney University of Pennsylvania, I worked as an Alcohol and Drug Intake Counselor at the Philadelphia Diagnostic Rehabilitation Center from 1985 to 1986. I joined DEA in 1986 as a Special Agent—and later a Resident Agent in Charge—at various Field Division Offices. After gaining extensive investigative experience in these roles, I was reassigned to DEA Headquarters in 2002 to become an Inspector. I made this move to continue my climb up the ranks: DEA employees with supervisory responsibilities are required to do a tour at DEA Headquarters. I then became a Senior Inspector for the Office of Professional Responsibility for the Newark Field Office. In this role, I led all DEA administrative and criminal internal affairs operations for the Northeast region (New York, New Jersey, Pennsylvania, Delaware, and the New England states). In June 2005, I returned to active operations as Assistant Special Agent in Charge of the Philadelphia Field Division. I held this position until April 2009, when I took a promotion and returned to DEA Headquarters as Deputy Chief Inspector for the Office of Professional Responsibility, where I led internal investigations for the entire DEA. In 2013, I switched back to an operations role, becoming Special Agent in Charge for the Washington Field Division. As Special Agent in Charge, I directed all DEA operations throughout the states of Maryland, West Virginia, Virginia, and the District of Columbia. Upon retiring in 2018, I started Colder Allied Consulting, LLC, a consulting business in Virginia.

controlled substance or list I chemical shall obtain annually a registration . . ."[6] Section 823 of the CSA sets forth factors to be considered by DEA prior to issuing a registration, which includes, among other things, that the registrant maintain "effective controls against diversion . . ."[7] If DEA determines that a registrant is not in compliance with the CSA, DEA has authority to revoke or suspend its registration, pursue administrative enforcement actions (*e.g.*, Letter of Admonition, Informal Administrative Hearing, Order to Show Cause), and to seek civil fines or criminal penalties in federal district court.[8]

DEA is also tasked with setting quotas—both in the aggregate and at the individual manufacturer level—for controlled substances.[9] By including the quota system in the CSA, Congress intended to "reduce or eliminate diversion."[10] Indeed, the purpose of quotas "are to provide for the adequate and uninterrupted supply for legitimate medical need of the types of schedule I and II controlled substances that have a potential for abuse, while limiting the amounts available to prevent diversion."[11]

D. Summary of Opinions

Based on my analysis—which has been informed by my 32 years of experience at DEA and my review of the materials cited throughout this report and in Exhibit B—I have formed the

[6] *See* 21 U.S.C. § 822(a)(1).
[7] *See* 21 U.S.C. § 823(a)(1).
[8] *See* 21 U.S.C. § 801 *et. seq;* Rubin, Paul D., et al, "*Chapter 23: Compliance with DEA Controlled Substance Requirements*," PLI, Health Care Mergers and Acquisitions Answer Book (2018); Gilbert, John A. & Houchk, Larry K., "*Chapter 17: Controlled Substances*," FDA Deskbook: A Compliance and Enforcement Guide (2018).
[9] *See* 21 U.S.C. § 826; 21 C.F.R. Part 1303.
[10] *See* Press Release, *DEA Reduces Amount Of Opioid Controlled Substances To Be Manufactured In 2017*, DEA (Oct. 4, 2016), *available at* https://www.dea.gov/press-releases/2016/10/04/dea-reduces-amount-opioid-controlled-substances-be-manufactured-2017.
[11] *Id.; see also* Apr. 11, 2019 Dep. of Stacy Harper-Avilla at 47:9-13 ("Q. What is the -- is it fair to say that one of the purposes of granting procurement quota is to ensure an adequate and uninterrupted supply of medications? A. It is one purpose.").

opinions described in this report to a reasonable degree of certainty. In general, those opinions include the following:

- DEA's suspicious order monitoring regulation and guidance is and has been vague and subjective, leaving registrants with significant discretion in creating their suspicious order monitoring systems.
- DEA did not provide meaningful guidance to registrants seeking more information on how to comply with their suspicious order monitoring obligations, leaving interpretation to the discretion of individual registrants.
- The claims of James E. Rafalski and Dr. Seth B. Whitelaw (two individuals retained by Track One Plaintiffs) that a compliant suspicious order monitoring system requires specific components has no basis in regulation and is inconsistent with DEA practice.
- If a company received no notification, action, or warning from DEA related to their suspicious order monitoring system even after regular audits, the registrant could expect that DEA did not find any violations of the relevant suspicious order monitoring laws and regulations.
- DEA's failure to allocate sufficient resources to the geographic areas in greatest need contributed to the growth of the opioid abuse crisis.
- DEA could have better responded to the opioid abuse crisis by allocating its resources in a more balanced manner across enforcement, diversion control, and community engagement.
- DEA did not effectively use its exclusive access to complete, aggregated ARCOS data to combat the opioid abuse crisis.
- DEA did not effectively utilize suspicious order reports submitted by registrants to identify targets contributing to the growth of the opioid abuse crisis.
- Illegal street opioids, most notably heroin and fentanyl, were and are DEA's primary focus during the opioid abuse crisis.
- Illicit sources for prescription opioids—such as pills mills, internet pharmacies, and doctor shopping—were and are a major cause of the opioid abuse crisis.[12]

II. DEA'S SUSPICIOUS ORDER MONITORING REGULATION AND RELATED GUIDANCE IS VAGUE AND SUBJECTIVE, LEAVING REGISTRANTS WITH SIGNIFICANT DISCRETION IN CREATING A COMPLIANT SUSPICIOUS ORDER MONITORING SYSTEM.

Among other things, the CSA creates a closed regulatory system that establishes strict controls over the manufacture, distribution, dispensing, or possession of controlled substances.[13]

[12] I reserve the right to amend or supplement this report based on any additional information that is brought to my attention, including, but not limited to, information from documents, expert reports, or testimony. If called to testify, I may use summaries and demonstratives (prepared and disclosed pursuant to the Court's scheduling orders) to assist my testimony.

[13] *See* 21 U.S.C. § 801 *et. seq.*

A person or entity must register with the DEA in order to become a part of this closed system.[14] The Attorney General is granted the authority to register an applicant to manufacture Schedule I or II controlled substances "if he determines that such registration is consistent with the public interest[.]"[15] In determining the public interest, the statute lists several factors to be considered, including:

> "maintenance of effective controls against diversion of particular controlled substances … into other than legitimate medical, scientific, research, or industrial channels, by limiting the importation and bulk manufacture of such controlled substances to a number of establishments which can produce an adequate and uninterrupted supply of these substances under adequately competitive conditions for legitimate medical, scientific, research, and industrial purposes[.]"[16]

The implementing federal regulation that addresses suspicious order monitoring has remained the same since it was promulgated in 1971:

> "The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."[17]

The DEA has issued some guidance about how to interpret the suspicious order monitoring regulation through formal letters provided to registrants,[18] presentations to individual companies at distributor briefings,[19] and presentations to registrants at industry conferences.[20] The DEA also provided guidance to Diversion Investigators about how to apply the CSA and federal

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14 *See* 21 U.S.C. § 822.
15 *See* 21 U.S.C. § 823(a).
16 *See* 21 U.S.C. § 823(a)(1).
17 *See* 21 C.F.R. § 1301.74(b).
18 *See, e.g.*, ALLERGAN_MDL_02467796 (the "2006 Dear Registrant Letter"); ALLERGAN_MDL_02187202 (the "2007 Dear Registrant Letter").
19 *See, e.g.*, US-DEA-00000143; US-DEA-00000588; US-DEA-00000214; US-DEA-00000367; US-DEA-00000368; US-DEA-00000378; US-DEA-00000386; US-DEA-00000404; US-DEA-00000469; US-DEA-00000933; US-DEA-00001043.
20 *See, e.g.*, DEA Presentation: *Effective Controls Against Diversion*, Manufacturer/Importer/Exporter Conferences (2013), *available at* https://www.deadiversion.usdoj.gov/mtgs/man_imp_exp/conf_2013/arnold.pdf; and DEA Presentation: *Manufacturer Trends & Updates*, Manufacturer Conference (2015), *available at* https://www.deadiversion.usdoj.gov/mtgs/man_imp_exp/conf_2015/prevoznik.pdf.

In cases of non-compliance, the registrant may receive a letter of admonition, in which case the registrant would have 30 days to respond and prove that corrective action was taken to remedy the problem identified. For more severe violations, DEA might take longer to inform the registrant of its findings. For example, DEA might develop a Memorandum of Understanding or Memorandum of Agreement with the registrant, which specifically identified corrective measures the registrant was required to take. But regardless of the specific approach, if DEA identified a regulatory violation, the registrant should learn about it during or after an audit. If a registrant received no specific feedback or follow-up after an audit, the registrant could expect that DEA did not identify any violations of the relevant laws or regulations.[97]

III. DEA COULD HAVE MORE EFFECTIVELY ALLOCATED ITS RESOURCES TO CURB THE GROWTH OF THE OPIOID ABUSE CRISIS.

As Special Agent in Charge, I was responsible for managing the budget for the Washington Division Office, which encompasses Maryland, West Virginia, Virginia, and the District of Columbia. In this role, I was tasked with requesting resources and developing proposals on how to allocate them to best fight the opioid abuse crisis. My opinions below draw from my experience (described in greater detail in Section I(A) and Exhibit A).

A. DEA failed to allocate sufficient resources to the geographic areas in greatest need.

Despite my best efforts, I was never able to obtain sufficient resources to provide the level of DEA operations my region required. The states under my purview required more resources than most other jurisdictions. My biggest area of concern was West Virginia, a state at the epicenter of

[97] I am not aware of any DEA actions—including civil or administrative actions, letters of admonition, notices of violation, orders to show cause, etc.—against Allergan Finance, LLC f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc., Cephalon, Inc., or Teva Pharmaceuticals USA, Inc., nor any of their current or prior affiliates or subsidiaries, at any time related to their suspicious order monitoring obligations.